



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,929	01/22/2002	Julie Straub	ACU 109 CIP	7093
23579	7590	10/07/2004	EXAMINER	
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361			WEBMAN, EDWARD J	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 10/07/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.



## UNITED STATES DEPARTMENT OF COMMERCE

## Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

10/053929

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
--------------------	-------------	-----------------------	------------------

EXAMINER

ART UNIT

PAPER NUMBER

9/4/04

DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/6/04☐ This action is FINAL.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 16-21 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 16-21 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of Reference Cited, PTO-892  
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6/19/02, 6/24/03  
☐ Interview Summary, PTO-413  
☐ Notice of Draftperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1617

Applicant's election without traverse of Group II, spray drying in the reply filed on 8/6/04 is acknowledged.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 18 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,395,300. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claim encompasses the instant claim regarding the form of the matrix.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al '574 in view of Unger (US 2001/0018072).

Art Unit: 1617

Gordon et al '574 teach a method of making dry powders comprising Hydrophobic and hydrophilic components comprising dissolving the hydrophobic component in an organic solvent, suspending the hydrophilic component, and spray drying (abstract). Hydrophilic drugs are disclosed (column 3 line 30). Hydrophilic excipients are specified, including sugars and polyvinylpyrrolidone (column 2 lines 49-51). Ethanol is disclosed (column 9 line 41).

Unger teaches a solid porous matrix comprising a surfactant, solvent and bioactive agent (abstract). Spray drying is specified (para 76). Organic solvents are disclosed (para 74). Polyvinyl pyrrolidone is specified as a surfactant (para 82). Ammonium bicarbonate is disclosed as a gaseous precursor (para 167).

It would have been obvious to one of ordinary skill in the art to include a hydrophilic excipient such as ammonium bicarbonate in the method of Gordon et al '574 to obtain *a porous particulate in view of Unger. On* the beneficial effect of obtaining ~~the~~ the PTO form 1449 filed 6/19/02, Ansel et al is lined through because only the title pages were provided. Arteaga et al, in Spanish, was only considered insofar as the English abstract. Traue et al in German was lined through because a brief description of its relevance was not provided.

No claims allowed.

Any inquiry concerning this communication should be directed to Edward J.

Webman at telephone number 571-272-0633.

EDWARD J. WEBMAN  
PATENT EXAMINER  
GROUP 1500